REMARKS

In response to the above-identified Office Action, Applicant amends the application and seeks reconsideration thereof. In this response, Applicant does not amend, cancel or add any claims. Accordingly, claims 14-18 are pending.

Attached hereto are clean unmarked replacement sections as well as a marked-up version of the same.

I. Drawings

The drawings have been objected to under 37 C.F.R. 1.183(a) for failing to show every feature of the invention specified in the claims. The Examiner states that "the blunting member lumen in communication with the flash chamber must be shown or the feature(s) canceled from the claim(s)." The Examiner further stated that "Applicant's specification describes a flash chamber 37 and housing 67 and drawings show that show the blunting member lumen in communication with the housing 67, but not with the flash chamber 37." The Applicant has amended the figures and specification to clarify the position of the flash chamber 91. The hub 37 had previously been improperly identified as a flash chamber. Figures 1, 2 and 4 have been amended to indicate that the flash chamber 91 is located in member 90 adjacent to the porous member 80. The specification has been amended to clarify that the structure 37 is a hub. Support for identifying the flash chamber as being part of member 90 is found in the original Figure 4 where the flash chamber is clearly identified as being part of member 90 adjacent to the porous member 80. Support for the identity of the hub is inherent to the Figures 1 and 2. It would be clear to one of ordinary skill in the art that the structure 37 as illustrated in Figures 1 and 2 can be described as a hub. The specification and the figures have been amended to clarify and properly identify the hub structure and a blunting member structure. Applicants believe that no new matter has been entered as a result of these amendments. Figure 4 as amended clearly shows that the lumen 48 of the blunting member is in communication with the flash chamber 91 through the flash chamber bore 92. Further, the specification has been amended at page 8 to correctly identify the engagement member

77 as illustrated in Figures, 1, 2 and 4 to be the engagement member. Accordingly, reconsideration and withdrawal of the objection to the drawings are requested.

II. Claims Rejected Under 35 U.S.C. § 103

Claims 14-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0630661 issued to Gomez (hereinafter "Gomez") in view of U.S. Patent No. 5,009,642 issued to Sahi, (hereinafter "Sahi") and European Patent No. 0353905 issued to Chang, hereinafter Chang. Applicants respectfully disagree for the following reasons.

In order to establish a *prima facie* case of obviousness, the Examiner must show that each of the elements of the claim are taught by the combined references. Claim 14 includes the elements of a blunting member disposed coaxially within the bore of the needle and the blunting member being axially movable within the bored needle. The Examiner admits Gomez does not disclose the hollow blunting member fitting within the needle bore as claimed in claim 14. The Examiner states that it would have been obvious to one of ordinary skill in the art to use a blunting member taught by Sahi in the device of Gomez. However, the Examiner does not explain how simply placing a blunting member within the needle of Gomez teaches a blunting member that is actually movable within a bore from a blunting position to a non-blunting position. Sahi teaches an apparatus that requires an end stop, flanges, a slide ferrule as well as holes cut through the housing in order to enable a blunting member to move within the bore of the needle from a blunting position to a non-blunting position. Neither Sahi nor Gomez teach how this apparatus can be combined with the flash chamber as taught by Gomez. Thus, Sahi cannot be combined with Gomez in order to teach the blunting member as claimed in claim 14. Chang does not cure this defect of Sahi and Gomez. Chang teaches merely a flash plug for use with catheters. Therefore, each of the elements of claim 14 are not taught or suggested by the cited references. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 14 are requested.

In regard to claims 15-18, these claims depend from independent claim 14 and incorporate the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 14, these

claims are not obvious over the cited references. Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 15-18 are requested.

III. Double Patenting

Submitted herewith is a corrected Terminal Disclaimer in compliance with 37 C.F.R. 1.321(c) to overcome nonstatutory double patenting grounds based upon U.S. Patent No. 6,210,379 issued to Solomon (hereinafter "Solomon"). This Terminal Disclaimer is a replacement for a prior inaccurate Terminal Disclaimer. This Terminal Disclaimer correctly states that Ethicon, Inc. is the owner of 100% interest in this application. Accordingly, reconsideration and withdrawal of the double patenting rejection are requested.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 14-18 patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207 3800.

Respectfully submitted,

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Dated: 10/1, 2002

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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Fee Amendment, Assistant Commissioner for Patents, Washington, D.C. 20231, on October 1, 2002.

Lillian E. Rodriguez 10-1-02

Lillian E. Rodriguez October 1, 2002.

SUBSTITUTE SECTIONS
MARKED-UP VERSION

BRIEF DESCRIPTION OF THE DRAWINGS

Features, aspects, and advantages of the invention will become more thoroughly apparent from the following detailed description, appended claims, and accompanying drawings in which:

Figure 1 is a cross-sectional view of an assembly incorporating a needle blunting apparatus according to an embodiment of the invention.

Figure 2 is a cross-sectional view of the needle component, the blunting member, and a porous member of the assembly of **Figure 1**.

Figure 3 is a cross-sectional view of a [flash chamber] hub used in the assembly of **Figure 1**.

Figure 4 is a cross-sectional view of the blunting apparatus of the assembly of **Figure 1**.

Figure 5 is a partial longitudinal sectional view of the blunting apparatus of assembly of **Figure 1**.

Figure 6 is a partial longitudinal sectional view of the needle component of the assembly shown in **Figures 1-3** having the needle blunting apparatus of the invention in its advanced "blunting" position.

Figures 7 through **9** are a step-wise illustration of one method of using the assembly described herein.

Figure 10 is a partial longitudinal sectional view showing the needle blunting apparatus.

DETAILED DESCRIPTION OF THE INVENTION

The following detailed description and the accompanying drawings are provided for the purpose of describing and illustrating presently preferred embodiments of the invention only, and are not intended to limit the scope of the invention in any way.

With reference to one embodiment of the invention shown in **Figures 1**[-] and **2**, there is provided assembly 10 that may be used to facilitate percutaneous insertion of an intravascular cannula, tube, and catheter. **Figures 1 and 2** show[s] assembly 10 generally comprises introducer 15, needle 18, needle blunting assembly 25, and protective outer sheath 16[(**Figure 1**)].

Introducer 15 comprises an elongated tubular cannula 30 with a hollow lumen 35 extending longitudinally through cannula 30. A tapered distal tip is formed on the distal end of the cannula 30 to facilitate insertion and advancement of the cannula through skin, connective tissue, or a blood vessel wall.

Assembly 10 also includes housing 67 coupled to needle blunting assembly 25. At the proximal end of housing 67, member 90 is coupled thereto. Member 90 has a lower cylindrical portion 91 that has an outside diameter that is smaller than the inner diameter of housing 67. Member 90 has a hollow lumen therethrough allowing porous member 80 to be positioned within member 90. Member 90 is at least partially transparent and the hollow lumen therethrough is in communication with the blunting apparatus 25. The lower cylindrical portion 91 serves as a flash chamber.

In the preferred embodiment, porous member 80 has a porosity approximately in the range of 35% to 55% and is preferably in the range of approximately 45%. This porosity prevents blood or other bodily fluids from exiting housing 67 and contacting a person such as

a healthcare worker for a certain time period such as thirty seconds. This time period should adequately protect a health worker such that bodily fluids do not fill the flash chamber [37] 91 wherein pressure build-up results in reverse-fluid pressure to the introducer 15.

Porous member 80 may be comprised of materials such as cotton high-density polyethylene (HDPE) or ultra-high-molecular-weight polyethylene (UHMWPE). Elongated rigid needle 18 is formed of material such as stainless steel hypotubing and has a beveled or otherwise sharpened distal tip 40. As shown in **Figures 2 and 4[3]**, a hollow bore 22 extends longitudinally through needle 18. A transparent flash chamber housing [37] 91 is coupled to the proximal end of the elongated rigid needle 18. A hollow flash chamber bore [38] 92 extends longitudinally through the [proximal] flash chamber [housing 37] 91. Such longitudinal flash chamber bore [38] 92 has a substantially cylindrical [proximal] distal inner wall of substantially continuous diameter and [a narrowed or tapered distal] enlarged cylindrical proximal inner wall [60]. Longitudinal [flash chamber] bore [38] 92 of flash chamber [housing 37] 91 is continuous with and connected to the hollow bore 22 of needle 18 as shown in **Figure [1] 4** wherein these elements coaxially nestle[d] together.

Figure 3 shows a hub 37 having a hollow hub bore 38 to enable the hub to be removably coupled to housing 67. The hub 37 is connected to introducer sheath 16 which includes cannula 30 having a hollow lumen 35. The hollow hub bore 38 extends longitudinally through the hub 37. The hub bore 38 has a substantially cylindrical proximal inner wall and a narrowed or tapered distal inner wall. The hub 37 is capable of receiving needle 18 such that needle 18 is coaxially nestled within sheath 16. The hub 37 has exterior rim 39 to engage a longitudinal portion 77 of the securing member 75 of the blunting apparatus.

Figure 4 shows needle blunting apparatus 25 of assembly 10 including an elongated tubular blunting member 65 preferably formed of rigid material such as stainless steel hypotubing. Blunting member 65 and needle 18 may form a single integral piece or they may be separate and secured together by methods known in the art. One such method involves blunting member 65 having a smaller outer diameter in comparison to the inner diameter of needle 18 such that blunting member 65 comfortably slides into needle 18 forming a secure member to pierce the skin or connective tissue of a human.

Blunting member 65 has a hollow lumen 48 that extends longitudinally therethrough. Blunting member 65 is coupled to or otherwise associated with securing member 75 such as a hook to anchor or hold the blunting member in its position. Other suitable configurations also may be used. Securing member 75 may be comprised of flexible or elastic material such as polymers including plastic. Securing member 75 has a longitudinal portion 77 that extends toward the distal end of blunting member 65. The longitudinal portion of securing portion 75 is positioned to press against the inner wall of housing 67 for blunting member 65.

Given the above description, the flow of bodily fluids through assembly 10 may occur generally in the following fashion. Needle 18 pierces the skin of a patient and enters a vessel such as a blood vessel. Blood or other bodily fluids enters the hollow cavity of needle 18 and moves generally in the direction of blunting member 65. Thereafter, the bodily fluid enters flash chamber [37]91. Flash chamber [37] 91 generally serves the purpose of containing bodily fluids. As flash chamber 37 fills with bodily fluid, the bodily fluid may contact porous member 80. While pressure builds in assembly 10, the bodily fluid follows a tortuous path through the pores or unobstructed paths in porous member 80. Porous member 80 prevents bodily fluid from exiting porous member 80 for a certain time period by absorbing

this fluid. For example, porous member 80 may prevent bodily fluids from escaping up to thirty seconds after flash chamber [37] 91 is completely filled.

It will be appreciated from **Figures 1** and **2** that the introducer 15, the needle component [20]18, and the blunting apparatus 25 are initially disposed in a coaxially nested arrangement wherein needle 18 extends coaxially through the lumen 35 of cannula 30. As noted above, blunting member 65 extends through a portion of the bore 22 of needle 18 such that the blunt distal tip 100 of blunting member 65 is located within the bore 22 of needle 18 a spaced distance X, proximal to its sharpened distal tip 100. Thereafter, pushing blunting assembly 25 in the direction of needle 18 will cause the blunting assembly 25 to be advanced in the distal direction as shown in **Figure 6**, while pulling blunting assembly 25 away from needle 18 will cause the blunting assembly 25 to be retracted in the proximal direction as shown in **Figure 5**. It will be appreciated that, when the blunting apparatus 25 is in its proximally retracted "non-blunting" position the blunt distal tip 100 resides within lumen 22 of the elongated rigid needle 18, a spaced distance X_1 from the distal tip 100 thereof. However, when the blunting apparatus 25 is moved to its distally advanced "blunting" position, the blunt distal tip 100 of the tubular member 65 will extend out of and beyond the sharp distal tip 100 of the elongate rigid needle 18 by a distance X_2. Such protrusion of the blunt distal tip 100 of the tubular member 65 beyond the sharpened distal tip 100 of the elongated rigid needle 18 essentially prevents the sharpened distal tip 100 of the elongate rigid needle causing trauma to, or puncturing, skin, or other tissue.

It will be appreciated that engagement member [52] 77 of the blunting apparatus 25 may be formed or configured in various different ways, without departing from its intended functions, including the function of facilitating movement of the blunting apparatus 25

between its proximally retracted "non-blunting" position as shown in **Figure 5**, and its distally extended "blunting" position as shown in **Figure 6**.

Figures 7 though **10** show one embodiment of the invention in which a catheter is inserted into a patient. With reference to **Figures 7** through **10** the blunting apparatus 25 is initially retracted to its "non-blunting" position as shown in **Figure 5**. Needle 18 having hub 37 and introducer [15]sheath 16 disposed thereon is then percutaneously inserted into a blood vessel BV, as shown in **Figure 7**. The presence of blood in the flash chamber provides an indication that blood vessel BV has been entered.

Thereafter, the blunting apparatus 25 is advanced to its distally advanced "blunting position" as shown in **Figure 6** and the needle 18 is withdrawn (**Figure 8**). Because the blunt distal tip 100 of the blunting member 65 of the blunting apparatus 25 extends to X_2, a distance that is beyond the beveled or sharpened distal tip 40 of the needle 18, the needle 18 is thereby rendered incapable of puncturing or causing trauma to the user or other persons who have occasion to handle a used needle 18.

After the needle 18 and blunting apparatus 25 have been removed and discarded, a tubular catheter C is advanced through the hub 37 and introducer sheath 16[15], as shown in **Figure 9**. **Figure 10** shows the hub introducer 15 is proximally withdrawn, leaving the catheter C within the blood vessel BV. After introducer 15 has been withdrawn, it resides about an exteriorized portion of the catheter C.

In the preceding detailed description, the invention is described with reference to specific embodiments thereof. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the

invention as set forth in the claims. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense.